

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0228]

Medical Devices; Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA." This guidance document represents the agency's current thinking on the technical content and clinical considerations for a premarket approval application (PMA) for an implantable middle ear hearing device (IMEHD). This guidance provides information to consider for developing the clinical studies and generating the scientific evidence that will provide reasonable assurance of safety and effectiveness of the IMEHD for its intended use. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.

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Display Date 6-11-02
Publication Date 6-12-02
Certifier A. Corbin

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1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eric Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080, ext. 187.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance describes the kind of information needed to allow FDA to evaluate the safety and effectiveness of an IMEHD. It is based in part upon current scientific knowledge, current FDA review criteria, and discussions and recommendations resulting from an Ear Nose and Throat Devices Advisory Panel Meeting that was held on June 18, 1999.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on IMEHD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

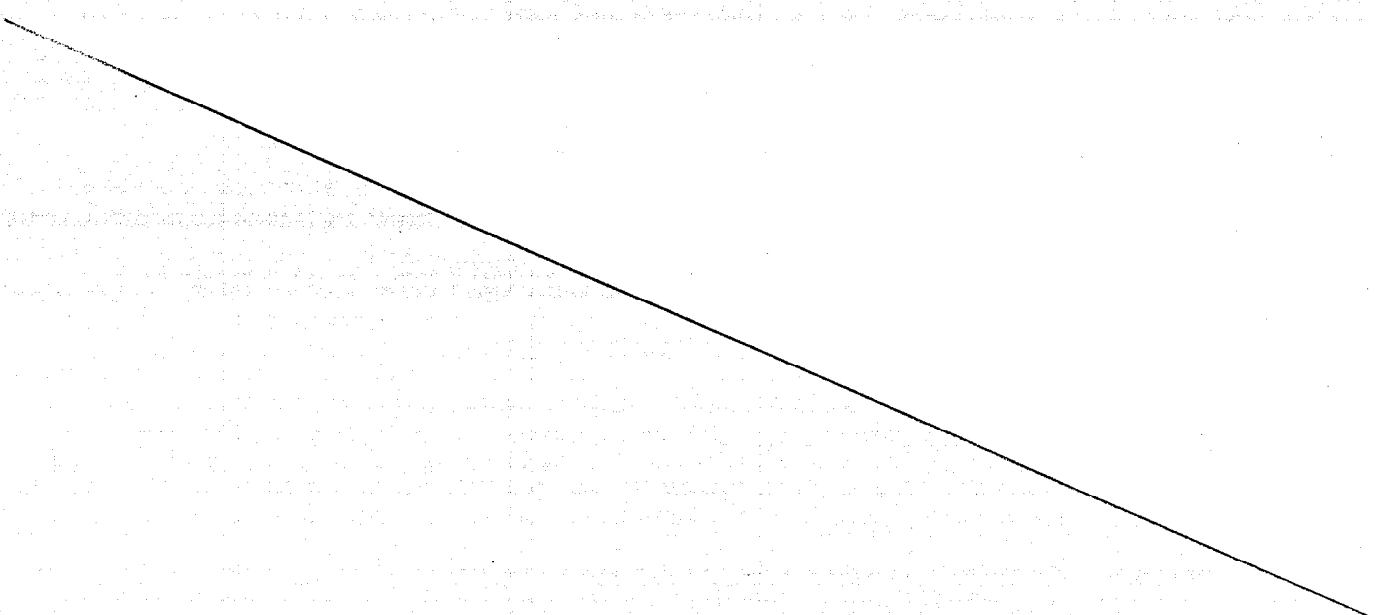
III. Electronic Access

In order to receive the "Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA," via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1406) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Internet site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the **Federal Register**]*. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 5/31/02

May 31, 2002.

Linda S. Kahan

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